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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,564	11/21/2007	John R. Schreiber	ABX-CW/2	6183

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,564	SCHREIBER, JOHN R.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3, 10, 13, 16-22, 26, 30, 36, 38-42, 44-47, 49, 53, 55-59, 64, 65, 67, 73, 75-77, 83, 86, 89, 97, and 101-109* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,10,13,16-22,26,30,36,38-42,44-47,49,53,55-59,64,65,67,73,75-77,83,86,89,97 and 101-109.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 10, 13, 16-22, 26, 30, 36, 38-42, 44-47, 57-59, 84, 85, and 97, 101-108, drawn to an isolated antibody, cell lines producing said antibody. NOTE: If this Group is elected, Applicant must also elect a single antibody for examination, e.g., an antibody which binds to a specific LPS and election of the amino acid sequence in claim 26, 36. This is a Restriction Requirement, not a species election.

Group II, claim(s) 49, 53, 55, 56, drawn to a method of prevention P.aeruginosa infection. NOTE: If this Group is elected, Applicant must also elect a single antibody to be used in the method for examination, e.g., an antibody which binds to a specific LPS and election of the amino acid sequence in claim 26, 36. This is a Restriction Requirement, not a species election.

Group III, claim(s) 64 drawn to a method for making an antibody comprising immunizing a non-human animal having incorporated a human immunoglobulin locus therein with a P.aeruginosa compostion. NOTE: If this Group is elected, Applicant must also elect a single antibody for examination, e.g., an antibody which binds to a specific LPS and election of the amino acid sequence in claim 26, 36. This is a Restriction Requirement, not a species election.

Group IV, claim(s) 65, 67, 73, 75-76, and 83, drawn to nucleic acids sequences, host cells, vectors and recombinant production methods. NOTE: If this Group is elected, Applicant must also elect a single DNA, e.g., SEQ ID NO: X or encodes antibody which binds specific LPS from specific strain. This is a Restriction Requirement, not a species election.

Group V, claim(s) 86 and 89, drawn to a non-human transgenic animal expressing a nucleic acid. NOTE: If this Group is elected, Applicant must also elect a single DNA to be expressed by the animal, e.g., SEQ ID NO: X or encodes antibody which binds specific LPS from specific strain. This is a Restriction Requirement, not a species election.

Group VI, claim 109, drawn to a method of detecting the presence of P.aeruginosa. NOTE: If this Group is elected, Applicant must also elect a single antibody for examination, e.g., an antibody which binds to a specific LPS and election of the amino acid sequence in claim 2626, 36. This is a Restriction Requirement, not a species election.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-VI are found to have no special technical feature that defines over the prior art of WO-A-02-20619 in view of Hatano et al (Infect.Immun. 1994, pp. 3608-3616). The first claimed invention is drawn to an isolated antibody or antigen-binding portion thereof which specifically binds to LPS from one of P.aeurginosa strains Fisher Devlin (International Serogroups) It-2 (011), It-3 (02), It-4 (01), It-5 (010), It-6 (07), PA01 (05), 170003 (02), IATS016 (02/05), and 170006 (02). WO-A-02-20619 describe an antibody made against the polysaccharide portion of the LPS O-specific side chain of International Serogroup Type 06ad (Fisher Devlin It-1) P.aeruginosa. This human Mab has strong avidity for 06-ad side chain PS, is opsonic for uptake and killing of the bacteria by PMN and is highly protective in preventing mortality in the neutropenic mouse model of pseudomonas sepsis. However, it does not specifically disclose the abs directed to the strains recited in instant claim 1. Hatano et al teaches vaccines derived from P.aeruginosa strains Fisher IT-1 (06), IT-3(02), IT-5(02), IT-6(07). See materials and methods. Hatano et al disclose that they are searching such vaccines to develop new strategies to reduce the complications due to these particular strains of P.aeruginosa (see page 3608, LH paragraph, lines 13-15). Hatano teach that the

vaccins are meant to be used for humans and this search in the direct active immunization with vaccines using the same noscomial strains as in the current application show the need of antibodies in passive immunization for treatment of P.aeurginosa infection. Therefore, it would have been obvious to use the methods taught in WO-A-02-20619 with the strains used in Hatano for the production of antibodies. Therefore, Applicant's invention does not contribute a special technical feature when viewed over the prior art of WO-A-02-20619 and Hatano. Accordingly, the inventions of groups I-VI do not have a single inventive concept and so lack unity of invention, and therefore the restriction for examination purpose as indicated is proper.

Additionally, Groups I, IV and V are directed to biologically, structurally and chemically different products, e.g., antibodies, DNA and a transgenic animal. These products do not have possess a single special technical feature. Additionally, there are patentably distinct products contained within each of these three groups, e.g., nucleotide sequences encoding different antibodies (as well as proteins comprising different amino acid sequences/encoded by different nucleic acid sequences, and antibodies which bind completely different structures/LPS) are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a species election requirement. The polynucleotide of group IV and the antibody of group I are patentably distinct for the following reasons. Polypeptides, such as the antibody of group IV which are composed of amino acids,

and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of group I and group IV would impose a serious search burden since a search of the polynucleotide of group I is would not be used to determine the patentability of an antibody of group IV, and vice-versa.

Inventions II, III and VI are unrelated as they comprise different special technical features. The methods are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The instant specification does not disclose that these methods would be used together. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis/detection differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions II, III and VI comprise different special technical features. Furthermore, the distinct steps and products require separate and distinct searches.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed(37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

8/17/09